**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF TEXAS**
**SAN ANTONIO DIVISION**

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| **UNITED STATES OF AMERICA ex rel. TIFFANY MONTCRIEFF, ROBERTA MARTINEZ, and ALICIA BURNETT,**<br><br>Plaintiffs,<br><br>vs.<br><br>**PERIPHERAL VASCULAR ASSOCIATES P.A.,**<br><br>Defendant. | Civil Action No. SA-17-CV-00317-XR |

**RELATORS' REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, PARTIAL SUMMARY JUDGMENT AGAINST DEFENDANT PERIPHERAL VASCULAR ASSOCIATES, P.A.**

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## I. INTRODUCTION

PVA spends most of its Opposition arguing that the AMA's CPT codes cannot serve as a valid basis for a False Claims Act case. It does so by ignoring the multitude of miscoding cases from this and other circuits, and by attempting to frame this as a "false certification" case instead of a case of fundamental factual falsity.

The American Medical Association's CPT Manual is the "Rosetta Stone" of the codes used to bill Medicare. *See Ohio Hosp. Ass'n v. Shalala*, 201 F.3d 418, 420 (6th Cir. 1999). When a provider inputs one of the AMA's 5-digit CPT codes on a bill to Medicare, it is "effectively submitting a claim for the services associated with that number in the AMA's CPT code set." *See United States v. Semrau*, 693 F.3d 510, 530 (6th Cir. 2012). If the provider knowingly uses a CPT code without having performed the services described in the AMA's CPT code set, a factually fraudulent claim has been submitted. The fact that the CPT descriptions themselves are not repeated in the Medicare statutes or regulations is irrelevant. As explained by the Sixth Circuit: "Congress directed the Secretary of Health and Human Services to . . . 'establish a uniform procedure coding system for the coding of all physicians' services,' [42 U.S.C.] § 1395w–4(c)(5). The Secretary acted on this authority by adopting the CPT code set drafted by the AMA. 45 C.F.R. § 162.1002." *Id.*

On thousands of bills submitted to Medicare, PVA lied about the services it had provided—misrepresenting that it had performed global vascular study services when it had not. As such, this is a case where the claims are "factually false," not "legally false." *See United States ex rel. Ruscher v. Omnicare, Inc.*, 663 F. App'x 368, 373 (5th Cir. 2016) ("A claim is factually false when the information provided to the government for reimbursement is inaccurate."). The "materiality" test for "legally false," "implied certification" cases, laid out by the Supreme Court in *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001, 195 L. Ed. 2d 348 (2016) (*Escobar*), is therefore irrelevant. Billing for the wrong service, or services not rendered, is always "material" for purposes of the FCA. *See, e.g., U.S. ex*

*rel. Sharp v. E. Oklahoma Orthopedic Ctr.*, No. 05-CV-572-TCK-TLW, 2009 WL 499375, at *6 (N.D. Okla. Feb. 27, 2009) ("[W]here the allegation is a factually false claim, any 'materiality' requirement would seem to be easily met in that the government paid a claim in a factually wrong amount, paid for a service that was not actually provided, or paid an amount greater than it should have based on the service actually provided.").

PVA's legal arguments are thus fundamentally flawed. And as to the facts and evidence submitted by Relators[1], PVA essentially concedes. For example, it does not dispute that for thousands of "testing only" patients, it had no record of a physician's interpretation prior to billing Medicare. Its only argument regarding the "testing only" patients is that because the government had the same records as Relators, and did not intervene in the case, the government must not care about its fraud. Oppo. [Docket No. 112] at 21-22. As detailed in the United States' Statement of Interest [Docket No. 113], the government's decision not to intervene is not reliable evidence of materiality (even if the *Escobar* materiality test applied). As multiple courts have explained, "The Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing." *United States ex rel. Longo v. Wheeling Hosp., Inc.*, No. 5:19-CV-192, 2019 WL 4478843, at *7 (N.D.W. Va. Sept. 18, 2019) (quoting case).

Similarly, PVA does not dispute that its own expert, Dr. Paul E. Collier, does not follow PVA's illegal billing practices. Instead, he interprets and signs every vascular study within 24 hours, and never bills until he has done so. Ex. 6[2] (Collier Dep. Tr.), at 39:14-40:15. Even one

[1] PVA complains of Relators' use of an Appendix, and argues that it attempts "to evade the Court's page limitations for motions for summary judgment." Oppo. at 3. To the contrary, Relators included an Appendix in accordance with Civil Local Rule CV-7.d.1. All of Relators' arguments and legal theories are contained in their brief, and all of their evidence is contained in the Declaration filed in support thereof. The Appendix organizes that evidence by issue, and includes, for example, citations to additional deposition testimony that reiterate those portions cited directly in Relators' brief.

[2] Unless otherwise noted, all referenced exhibits are attached to the Declaration of Sarvenaz Fahimi, filed with Relators' Motion [Docket No. 95-2].

of PVA's former physicians, Dr. Lyssa Ochoa, testified: "You cannot bill for the physician's services until you have finalized that report." Ex. 8 (Ochoa Dep. Tr.), at 33:8-9.

PVA also does not dispute that it billed for both E/M services and vascular studies without having a "separate distinctly identifiable signed written report" as required by the CPT manual. Instead, PVA argues that the requirement has nothing to do with scans performed in conjunction with E/M visits, but only relates to interpretations by a physician that "had no other involvement with the performance of the study." Oppo. at 11-12. PVA's argument borders on frivolous, and relies on selective quotation. The "separate distinctly identifiable signed written report" requirement is contained in the "E/M" section of the CPT manual, in a paragraph that makes clear that it is describing what to do when a study is performed pursuant to a patient encounter:

> The actual performance and/or interpretation of diagnostic tests/studies ordered during a patient encounter are not included in the levels of E/M services. Physician performance of diagnostic tests/studies for which specific CPT® codes are available may be reported separately, in addition to the appropriate E/M code. The physician's interpretation of the results of diagnostic tests/studies (ie, professional component) *with preparation of a separate distinctly identifiable signed written report* may also be reported separately, using the appropriate CPT® code with modifier 26 appended.

Ex. 45, at p. 6 (emphasis added). Moreover, as detailed below, the CPT manual repeatedly states that review of diagnostic tests is part of the E/M service.

Not only is PVA's interpretation facially absurd, but it was created solely for purposes of litigation. There is not a shred of evidence in the record suggesting that PVA's employees held any of the interpretations they now assert. To the contrary, as detailed in Relator's Motion, PVA knew what the rules were, as evidenced by its practices when performing work under contract with area hospitals (*see* Ex. 18), and by its own 2017 "compliance billing" project (*see* Ex. 30, at DEF007691). PVA's Opposition is conspicuously silent on both.

These are just a few of the facts that PVA has not controverted, because it cannot. Accordingly, Relators respectfully request summary judgment on the following categories of claims:

(1) 8,757 claims for vascular studies performed on "testing only" patients, submitted by Defendant to Medicare and other federal payers using false CPT codes that misrepresented that a physician's interpretation and reporting had been rendered;

(2) 55,566 claims for vascular studies (including 29,954 claims to Medicare Part B, and 25,301 claims to Medicare Advantage Plans) related to patients on which PVA conducted both an "Evaluation and Management" patient visit and a vascular study on the same day, where PVA illegally billed Medicare and other federal payers for both, without having completed a separate, stand-alone report reflecting performance of the professional component (i.e., double billing); and

(3) 1,690 claims for vascular studies to Medicare and other federal payers on which PVA misrepresented the identity of the physician who performed interpretation of the vascular studies.

Relators further alternatively seek partial summary judgment as to all elements of PVA's violations of the False Claims Act *other than* whether PVA violated the False Claims Act "knowingly"; i.e., reserving only determination of the element of scienter for the trier of fact.

## II. ARGUMENT

### A. PVA's bills were false.

#### 1. Failure to provide the services described in the CPT manual gives rise to factually false claims.

PVA argues that its claims were not false because no Medicare statute or regulation requires preparation of a written report. The argument misses the mark, because it assumes the framework of a "legally false" claim, rather than a "factually false" claim. As explained by the Fifth Circuit:

> FCA claims can be either legally false or factually false. *E.g., United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1266 (D.C. Cir. 2010) (recognizing factually false claims as "the paradigmatic case" and legally false claims as the "certification theory"). A claim is factually false when the information provided to the government for reimbursement is inaccurate. [Citation.] A claim is legally false when "a claimant ... falsely

> certifies compliance with [a] statute or regulation." *See United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997).

*United States ex rel. Ruscher v. Omnicare, Inc.*, 663 F. App'x 368, 373 (5th Cir. 2016)

PVA's FCA violations are based first and foremost on the false information that it submitted on its CMS-1500 forms. Using a CPT code that misrepresents the services provided on a bill to Medicare is a factually "false" claim for purposes of the FCA, as it constitutes billing for services not performed, or misrepresenting the services performed. *See, e.g., U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 192 (5th Cir. 2009) ("Also alleged are specific dates that each doctor falsely claimed to have provided services to patients and often the type of medical service or its Current Procedural Terminology code that would have been used in the bill."); *U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 662 (S.D. Tex. 2013); *United States ex rel. Emerson Park v. Legacy Heart Care, LLC*, No. 3:16-CV-0803-S, 2019 WL 4450371, at *9 (N.D. Tex. Sept. 17, 2019) ("Relator alleged that Remaining Defendants are liable under the FCA for 'upcoding [E&M] services to the highest level billing codes'—i.e., charging Medicare for unnecessary services or services that were never actually provided. A defendant charging the Government for services not actually provided is a staple FCA violation."); *United States v. Wagoner*, No. 2:17-CV-478-TLS, 2018 WL 4539819, at *5 (N.D. Ind. Sept. 20, 2018); *United States ex rel. Turner v. Michaelis Jackson & Assocs.*, No. 03-CV-4219-JPG, 2007 WL 496384, at *7 (S.D. Ill. Feb. 13, 2007) ("relators have shown why the bill submitted to Medicare was false: it was billed pursuant to CPT 99213 rather than CPT 66984"); *Krizek*, 859 F. Supp. at 7–8.

As explained by the Sixth Circuit Court of Appeals in an opinion affirming the criminal conviction of a physician for Medicare fraud, though the CPT codes and their definitions are published by a private organization (the AMA), their misuse logically gives rise to legal liability. *See United States v. Semrau*, 693 F.3d 510, 530–31 (6th Cir. 2012). In *Semrau*, the defendant physician argued that "misuse of CPT codes cannot constitute criminal conduct because they are the product of a private organization and have not been formally promulgated by the government." *Id.* at 530. The Sixth Circuit disagreed, explaining as follows:

> As an initial matter, it seems clear that the CPT codes themselves create no laws or liability but are merely a government-sanctioned means of summarizing several pieces of information into a concise, standardized number. Congress directed the Secretary of Health and Human Services to "prescribe such regulations as may be necessary to carry out the administration of" Medicare, 42 U.S.C. § 1395hh(a)(1), and to "establish a uniform procedure coding system for the coding of all physicians' services," *id.* § 1395w–4(c)(5). The Secretary acted on this authority by adopting the CPT code set drafted by the AMA. 45 C.F.R. § 162.1002. Dr. Semrau's attorney himself acknowledged during the trial that CPT codes "are simply a shorthand way of incorporating the description of the service." Thus, when Dr. Semrau submitted a claim for "99312," he was effectively submitting a claim for the services associated with that number in the AMA's CPT code set, as defined above.
>
> It is illogical to suggest that a person could escape liability because a claim comes in the form of a number instead of the words directly associated with that number. This is particularly true for the statute in question because "[t]he broad language of § 1347 shows that Congress intended for this statute to include within its scope a wide range of conduct so that all forms of health care fraud would be proscribed, regardless of the kind of specific schemes unscrupulous persons may concoct." *United States v. Lucien,* 347 F.3d 45, 51 (2d Cir.2003). In short, § 1347 "is simply a fraud statute." *United States v. Franklin–El,* 554 F.3d 903, 911 (10th Cir.2009). "Although the health care fraud statute does not (and could not) specify the innumerable fraud schemes one may devise," *id.* at 910–11, it is difficult to imagine a more obvious way to commit healthcare fraud than billing for services not actually rendered. Indeed, this court and other circuits have previously upheld convictions for CPT "upcoding." [Citations].

*Id.* at 530–31.

When PVA billed using the global CPT codes, it was representing that it had completed a physician's interpretation, and a written report reflecting the physician's interpretation. Yet for 24.2% of its global billings, a PVA physician had not prepared and signed a final report in MedStreaming. As PVA's internal policies emphasize, "If it is not documented, it never happened and cannot be billed." Ex. 20, at DEF000694. PVA was thus falsely representing via submission of the global CPT codes that it had rendered the complete global service.

**2. Notes in the AllScripts patient visit record do not absolve PVA.**

Although conceding that a vast number of MedStreaming reports were not completed before billing Medicare, PVA argues that in those instances its physicians' written reports exist outside of MedStreaming, in notes that accompany a visit (which are housed in PVA's

"AllScripts" system). This defense fails with respect to both the "testing only" patients, and the E/M and testing patients, as described in the following sections.

**a. PVA has no defense to the "testing only" violations.**

As detailed in Relators' Motion, for PVA's "testing only" patients, there is nowhere besides a MedStreaming report that the PVA physicians' interpretations could appear. *See* App. Nos. 11-14; 30. Using PVA's medical record and billing data, Dr. Nye has calculated that PVA submitted 11,728 charges for vascular studies performed on "testing only" patients, for which there was no signed MedStreaming report at the time the charge was submitted. *See* Ex. 200 (Nye Supp. Report) at Ex. 2; App. No. 33. Of those, 8,757 were to Medicare.[3] All of those claims are false.

PVA does not dispute these facts, and provides no explanation or defense, other than its general attacks on the CPT manual.[4]

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[3] PVA argues that the "discrepancies" between the 11,728 and 8,757 number "underscore the unreliability of" Relators' damage calculations. Oppo. at p. 21, n. 20. PVA did not read Relators' Motion carefully enough: 11,728 is the number of "testing only" false claims included in all of the data PVA provided, which included some non-governmental insurance company payers. *See* Mot. at p. 10, n. 2 ("These claims are filtered down to Medicare-payors in Section II.E below."); The 8,757 figure is simply the subset that were submitted to Medicare payers. *See* Mot. § II.E; Ex. 207.

[4] In its affirmative Motion for Summary judgment, PVA *admits* that it has no defense to these "testing only" cases. Instead, PVA attempts to dismiss them as "a palpably low percentage of PVA's business." PVA's Mot. at 21. Because they "only account for 4.9%" of these tests, PVA argues that "[a]n error rate that low does not support an argument that PVA engaged in a fraudulent scheme to cheat the Government, and, in fact, supports the opposite conclusion." *Id.* This remarkable proposition—that false billings do not violate the FCA so long as they are a relatively small percentage of total claims—is without support. The sole case that PVA cites on this point, *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1034 (D. Nev. 2006), makes the point that a low error rate would tend to negate the element of *scienter*. But a low rate of false billings is not probative of falsity itself.

In any event, PVA is using the wrong metric: its "error" rate is not 4.9%. Instead, the pertinent percentage is 24.2%: Across all vascular studies, whether "testing only" or testing plus E/M visit, PVA billed without a final interpretation 24.2% of the time, tainting 29.5% of the reimbursement payments it received (including 29.89% of all payments from Medicare Part B). *See* Ex. 200 (Nye Supp. Report), at Exs. 2 & 4d; App. No. 26. An "error rate" that high—a quarter of all tests—cuts against PVA's claim of mere negligence. Other than suggesting that it was merely negligent, PVA's motion includes no defense as to the "testing only" patients.

**b. PVA miscomprehends Relators' "double dipping" damages calculation.**

As to patients who had both a vascular study and an Evaluation and Management (E/M) visit, the vascular study cannot be billed for in addition to the E/M code unless there is a separate, stand alone report reflecting a physician's interpretation. PVA repeatedly violated this requirement, ultimately submitting 55,566 charges to federal payors for vascular studies on top of E/M visit charges, without a separate interpretive report. *See* Ex. 207.

In its Opposition, PVA argues that "Relators fail to show how any claim submitted by PVA for E/M services was false." Oppo. at p.10. PVA is confused. The 55,566 charges presented by Relators are not charges for E/M service, but charges for vascular studies that were billed *in addition to* E/M services. This is laid out in the second table on pages 29 and 30 of Relators' Motion. That table summarizes data from Exhibit 207, comprised of "data extracted from Exhibits 4d Supplemental and 11 of the Second Supplemental Report of Dr. Nye, with non-federal and non-Medicare payors filtered out." Oppo. at 30. The Second Supplemental Report of Dr. Nye clearly explains that the calculations contained in Exhibit 4d Supplemental, and Exhibit 11, reflect payments and billing from PVA's "Billing System Data **for Imaging** . . ." Ex. 201 (Nye. 2nd Supp.), ¶¶ 2.ii, 2.ix (emphasis added). Dr. Nye's calculations regarding the payments and claims for E/M services are reflected elsewhere (e.g., Exhibits 6a.i Supplemental, 6d Supplemental).

In short, as to the double-dipping category, Relators do not seek damages for the amounts PVA billed for E/M services, but only for vascular studies billed on top of those E/M services in contradiction of the billing rules.

**c. PVA's interpretation of the double-dipping prohibition is frivolous.**

PVA also argues that the CPT manual does not in fact prohibit billing a vascular study on top of an E/M visit without a standalone report. The plain language of the CPT manual is to the contrary:

> The actual performance and/or interpretation of diagnostic tests/studies ordered during a patient encounter are not included in the levels of E/M services. Physician performance of diagnostic tests/studies for which specific CPT® codes are available may be reported separately, in addition to the appropriate E/M code. The physician's interpretation of the results of diagnostic tests/studies (ie, professional component) *with preparation of a separate distinctly identifiable signed written report* may also be reported separately, using the appropriate CPT® code with modifier 26 appended.

Ex. 45, at p. 6 (emphasis added). This paragraph is found within the "E/M" section of the CPT manual.

PVA argues that this paragraph applies where, for example, "a radiologist reads an X-Ray or MRI performed in a hospital. The radiologist is typically not involved in the patient care, and her only association with the patient is interpreting the X-Ray or MRI. That professional component only would be reported with a 'modifier 26 appended.'" Oppo. at 12. PVA's sole support for its argument is the opinion of its coding expert, Melissa Scott. Ms. Scott, in turn, cites no authority for her interpretation. Nor does PVA provide any contemporaneous evidence that PVA's employees actually understood the CPT manual to mean what they now assert.

In contrast, multiple industry publications cited by Relators confirm the plain language reading of the paragraph. *See, e.g.,* Ex. 43, American Urological Association & American Institute of Ultrasound in Medicine, *Medical Documentation Requirements: Diagnostic Urologic Ultrasound and Ultrasound-Guided Procedures,* at ALEXANDER000099 ("The American Medical Association clarified that if an imaging test is performed on the same day as an Evaluation & Management (E&M) service, that each should be separately documented and billed, as stated in the E&M Services Guidelines Section in the CPT® book.").

Moreover, PVA's other expert—Dr. Paul Collier—does exactly what the CPT manual requires when conducting an E/M visit and a vascular study: he completes two separate reports, and does so before billing. Ex. 6 (Collier Dep. Tr.), 43:17-44:7, 49:22-50:4.

The requirement of a separate distinctly identifiable signed written report makes sense, because the CPT manual repeatedly makes clear that routine review of diagnostic tests is already part of the E/M visit. As detailed in the E/M section, there are seven components to an E/M visit

that are used to determine which E/M code should be billed: history, examination, medical decision making, counseling, coordination of care, nature of presenting problem, and time. *See* Ex. 209 to the Declaration of Sarvenaz Fahimi in Support of Relators' Reply in Support of Motion for Summary Judgment, filed herewith, at 2. Review of diagnostic tests—such as the vascular studies at issue here—is included in several of these components. For example, "counseling" is defined as "a discussion with a patient and/or family concerning one or more of the following areas: diagnostic results, impressions, and/or recommended diagnostic studies." *Id.* Similarly, "medical decision making" is defined as "the complexity of establishing a diagnosis and/or selecting a management option as measure by" several factors, including "the amount and/or complexity of medical records, diagnostic tests, and/or other information that must be obtained, reviewed, and analyzed . . ." *Id.* at 7; *see also* Ex. 196 (Alexander Report) at 47-48 ("A professional component billing based on a review of the findings of these procedures, without a complete, written report similar to that which would be prepared by a specialist in the field, does not meet the conditions for separate payment of the services. This is because the review is already included in the E/M payment."). It is thus logical that in order to bill for a separate service, the physician must do more than they are already expected to do as part of the E/M visit.

PVA has no credible or logical defense to the falsity of its duplicate billings.

**d. Claims billed under the wrong provider are factually false.**

In addition, the claims that PVA submitted under the wrong provider's name are false. PVA makes two arguments in response. First, PVA suggests that Dr. Nye's analysis is unreliable. Oppo. at 13. But PVA provides no specific or general explanation for what is inaccurate about Dr. Nye's analysis. Dr. Nye used PVA's data to find mismatches between the "billing MD" field and the "reading MD" field. PVA suggests this approach is flawed, but does not explain why. PVA's discovery responses and internal documents indicate that those fields are exactly what their name indicates. *See* Ex. 36 to the Declaration of Sarvenaz Fahimi, filed herewith, at 5 ("*Reading MD* – The physician that finalized the study in Medstreaming."); *id.*,

Ex. 208 (Key to the AllScripts billing data, indicating that the Column Header, "Billing_Dr. Name," means "Billing Provider").

Second, PVA argues, without citation to any authority, that billing under the wrong physician is a "'garden-variety' regulatory issue" that should not give rise to FCA liability. To the contrary, billing under the wrong physician's name constitutes a false claim. *See United States v. Mackby*, 261 F.3d 821, 826 (9th Cir. 2001) ("a claim may be false even if the services billed were actually provided, if the purported provider did not actually render or supervise the service.") (citing *Peterson v. Weinberger,* 508 F.2d 45, 52 (5th Cir.1975)). Moreover, Medicare makes clear that it considers billing under the wrong provider, to be a quintessential example of fraud and abuse. For example, the Medicare Program Program Integrity Manual, Chapter 4 – Program Integrity, provides a detailed list of "Examples of Medicare Fraud," including "Misrepresenting dates and descriptions of services furnished or the identity of . . . the individual who furnished the services." Ex. 205, § 4.2.1.

An internal 2013 e-mail string also confirms that PVA knows its charges must be billed under the physician who actually read the study. *See* Ex. 16 ("Dr. Macris is the one who read the study, so the lab should be billed under him.").

With respect to 1,690 claims, PVA not only submitted global CPT codes when the physician had not completed and documented their interpretation, but PVA also billed under the wrong rendering physician. Those claims were false for purpose of the FCA.

**e. *Swafford* is inapposite.**

By cross-reference to its Motion papers, PVA relies heavily on a vascular study case from the Western District of Michigan: *U.S. ex rel. Swafford v. Borgess Med. Ctr.*, 98 F. Supp. 2d 822, 824 (W.D. Mich. 2000), *aff'd*, 24 F. App'x 491 (6th Cir. 2001). Though transpiring within the same specialty, the alleged fraud at issue in *Swafford* is factually distinct from what is alleged here, and that distinction merely highlights the falsity of PVA's conduct. In *Swafford*, the relator did not allege that the physicians failed to complete a stand-alone report before billing. Instead,

the relator alleged that the physicians did not put sufficient thought and care into those reports. *Id.* at 826.

> [P]laintiff contends the physicians merely reworded and/or plagiarized the technician's or technologist's "worksheet" to prepare a physician's ultrasound report. Defendant physicians then billed the government through Champus, Medicare or Medicaid for these "interpretations" which, according to plaintiff, constituted mere plagiarism of the worksheet prepared by the technician/technologist.

*Id.* The relator argued that the physicians, instead of relying on the technologists' worksheets, were required to review and interpret all of the raw data and images in preparing their final reports. *Id.* at 829. The court disagreed, finding no enforceable requirement that the physician review the raw data instead of a technologist's summary of that data. *Id.* at 829-31.

Here, each of the three categories of PVA's false claims stands in stark contrast to *Swafford*:

First, as to the claims for "testing only" patients, there was no report at all. Accordingly, there is no dispute about the quality of the interpretation, as there is no evidence of any interpretation having been done at all. Those claims thus fall squarely within the "actual falsehood" category that the court in *Swafford* found inapplicable. *See Swafford*, 98 F. Supp. 2d at 831-32 (explaining that the relator failed to present evidence amounting to a "factual claim as to whether defendants (at a minimum) actually performed some work by reading and/or reviewing work performed by the technician/technologists.").

Second, as to the false claims for vascular studies performed in conjunction with E/M visits but without a stand-alone report, while there is nothing in the CPT code definitions that mandates an interpreting physician review the raw data as the relator asserted in *Swafford*, there *is* an explicit requirement that a "separate distinctly identifiable signed written report" be produced in order to bill for a vascular study on top of an E/M visit.

Third, as to the false claims with the wrong rendering provider, such claims are factually false, and do not rely on any qualitative or subjective analysis. *See United States v. Mackby*, 261 F.3d 821, 826 (9th Cir. 2001).

In sum, *Swafford* boiled down to "plaintiff's disagreement with the qualitative nature and degree of review necessary for defendant physicians to claim to 'interpret'" vascular studies. 98 F. Supp. 2d at 833. Here, in contrast, PVA falsely billed for services that are described in the CPT manual but were not rendered.

**B. PVA acted knowingly.**

Relators' Motion presented a variety of evidence demonstrating that PVA acted recklessly, in deliberate ignorance, and even with actual knowledge, that it was submitting false claims. PVA's Opposition is silent on most of that evidence. The few rebuttals it offers are unconvincing.

As to PVA's brief 2017 move towards "compliance billing," detailed in section II.F.1 of Relators' Motion, PVA seems to argue that the evidence surrounding those efforts are not sufficiently linked to particular individuals at PVA. To the contrary, the documents evidencing that 2017 compliance program were drafted by PVA's Vascular Lab Committee. The Vascular Lab Committee is comprised of PVA's CEO, President, Medical Directors, Technical Director, and Business Development Officer. *See* Ex. 10 (Hembling Dep. Tr.), at 13:5-14:1. They are not mysterious, one-off documents created by a rogue employee with no control over the business.

Moreover, the "collective knowledge" concept that PVA relies on is particular to the false certification context. The primary case relied upon by PVA, *U.S. ex rel. Ruscher v. Omnicare, Inc*., No. 4:08-CV-3396, 2015 WL 5178074 (S.D. Tex. Sept. 3, 2015), *aff'd sub nom.,* 663 Fed. Appx. 368 (5th Cir. 2016), is a "legally false" FCA case involving false certifications and kickback allegations.

As explained by the district court in *Ruscher*:

> In a false certification case, like this one, this requirement [of showing a particular individual knew of the falsity] is best understood to require that Relator show someone at Omnicare who 1) knew that the company certified its compliance with the AKS in connection with Medicaid claims and 2) had knowledge of the AKS violations. Relator has evidence that many individuals at Omnicare knew generally that the company had a duty to comply with the AKS, a criminal statute.

*Id.* at *29. The court went on to state, "without knowledge of certification by someone at Omnicare, there is no fraud." *Ruscher*, 2015 WL 5178074 at *29.

This case is not a false certification case. Accordingly, no such "knowledge of certification" test applies to the claims against PVA. Instead, Relators must only show that PVA knew of the factual falsity of the claims it was submitting; i.e., that it was submitting claims for payment without a physician's interpretation. There is no dispute that PVA was doing so, and that everyone knew it—it was PVA's standard practice, established by its Vascular Lab Committee.

With respect to evidence that PVA's practices ran afoul of its own internal compliance policies, PVA first argues that there is no requirement that PVA have compliance policies in place. PVA misses the point. Whether or not written compliance policies were required, if there are policies in place, those policies are logically indicative of the organization's understanding of the rules than govern its business. PVA next argues that its compliance policies demonstrate that it had no intent to defraud Medicare. Setting up compliance policies, however, demonstrates quite the opposite if those policies are ignored. For example, Martha McGee, PVA's Billing Supervisor, who has been with PVA for 14 years, testified that PVA's "Medical Documentation and Coding Compliance Pledge" did not look familiar to her. Ex. 9 (McGee Dep. Tr.), at 20:2-11. Similarly, PVA's Compliance Officer, Dr. Alsabrook, testified that PVA does not actually engage in the internal billing audit procedure laid out in its Compliance Manual. Ex. 1 (Alsabrook Dep. Tr.), at 21:17-21. And when PVA's Vascular Lab Committee finally took up the issue in 2017, it abandoned the "Compliance" project within a matter of months. *See, supra*, § II.E.1. Accordingly, PVA's "teams, committees, and processes" demonstrate not that it acted innocently, but that it acted with full knowledge, or at least in reckless disregard or deliberate ignorance, of the billing requirements and its violations thereof.

Apart from these thin arguments, PVA does not even attempt to rebut Relators' evidence of *scienter*, including the fact that:

(1) Every Medicare and industry publication touching the issues makes clear that PVA's practices were out of bounds;

(2) Even PVA's own expert, Dr. Collier, does not follow PVA's practices;

(3) When a third party was watching—i.e., the hospitals with which it contracted—PVA actually followed the rules, completing written reports within—at most—48 hours of the study being performed, and always billing after a final report is complete in MedStreaming;

(4) Internal e-mails show that before 2014, PVA awaited final reports before billing, *see, e.g.,* Exs. 12, 14;

(5) PVA closely tracked delays in physician interpretation and reporting of vascular studies, and knew that studies were not being read; and

(6) PVA practices violated the standards of its accreditation body, the Intersocietal Accreditation Commission, and the American College of Radiology.

PVA's Opposition is conspicuously silent on all of this evidence. Finally, PVA does not provide a single piece of evidence to suggest that its employees actually held the beliefs that it now espouses. *Cf. United States v. Crain*, 877 F.3d 637, 650 (5th Cir. 2017) ("Crain presents only self-serving *post hoc* assertions about how he would have pled. The contemporaneous evidence at the time he pleaded guilty, by contrast, does not weigh in his favor."); *Hansen v. Aon Risk Services of Texas*, 473 F. Supp. 2d 743, 753 (S.D. Tex. 2007) ("The summary judgment evidence shows that defendant has little contemporaneous evidence to support the nondiscriminatory reason for which it claims to have discharged plaintiff, and that the evidence defendant does have tends to support plaintiff's version of the facts.").

PVA fails to negate compelling evidence that it knew it was routinely submitting claims for services it had not provided.

**C. PVA's false statements were material.**

PVA next argues that its violations were not material, relying on the *Escobar* test. *See Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2001, 195 L. Ed. 2d 348 (2016). The *Escobar* materiality test, however, only applies to "implied certification" cases:

> Accordingly, we hold that the implied certification theory can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.

*Id.*

As detailed above, this is not a case of "implied certification" or "legal falsity." *See United States ex rel. Ruscher v. Omnicare, Inc.*, 663 F. App'x 368, 373 (5th Cir. 2016). Instead, it is a case of factual falsity, and billing for the wrong service, or services not rendered, is always "material" for purposes of the FCA. *See, e.g., U.S. ex rel. Sharp v. E. Oklahoma Orthopedic Ctr.*, No. 05-CV-572-TCK-TLW, 2009 WL 499375, at *6 (N.D. Okla. Feb. 27, 2009) ("[W]here the allegation is a factually false claim, any 'materiality' requirement would seem to be easily met in that the government paid a claim in a factually wrong amount, paid for a service that was not actually provided, or paid an amount greater than it should have based on the service actually provided.").

Moreover, even if analyzed under the framework of *Escobar*, PVA's submissions on the CMS-1500 forms meet the *Escobar* test. As recently explained by the Eleventh Circuit in a healthcare fraud FCA case dealing with skilled nursing facilities ("SNFs"):

> SNFs receive money from Medicare based on the services they provide. In this case, the SNFs indicated they had provided more services—in quantity and quality—than they, in fact, provided. Therefore, Medicare paid the SNFs higher amounts than they were truly owed. This plain and obvious materiality went to the heart of the SNFs' ability to obtain reimbursement from Medicare.

*Ruckh v. Salus Rehab., LLC*, 963 F.3d 1089, 1105 (11th Cir. 2020). The same is true of PVA: it indicated that it "had provided more services" than it had, and as a result, Medicare paid "higher amounts than they were truly owed." *See id.*

Even post-*Escobar*, the Fifth Circuit requires "proof only that the defendant's false statements could have influenced the government's pay decision or had the potential to influence

the government's decision, not that the false statements actually did so." *U.S. ex rel. Harman v. Trinity Industries Inc.*, 872 F.3d 645, 661 (5th Cir. 2017). As detailed above, Medicare reimburses for services rendered based on charges submitted by providers on the CMS-1500 form, using CPT codes. The CPT codes determine the amount of money that Medicare reimburses the provider. There is no other mechanism or documentation that triggers Medicare's reimbursement. Accordingly, there can be no dispute that the CPT codes submitted by PVA "could have influenced the government's pay decision." *See id.*

Moreover, Medicare makes clear in various publications that it considers billing for services not rendered, and naming the wrong provider,[5] to be quintessential examples of fraud and abuse. For example, CMS publishes a manual for providers entitled "Medicare Fraud & Abuse: Prevent, Detect, Report," which reminds providers, among other things:

- "**When you submit a claim for services provided to a Medicare beneficiary, you are filing a bill with the Federal Government and certifying you earned the payment requested and complied with the billing requirements**."
- "Examples of improper claims include: . . . Billing codes that reflect [] a more expensive treatment than was provided. . . . Billing services not provided. . . . Billing separately for services already included in a global fee, like billing an evaluation and management service the day after surgery."
- "'If you didn't document it, it's the same as if you didn't do it.' The same can be said for Medicare billing."

Ex. 204, at 11 (emphasis in original)

The Medicare Program Program Integrity Manual, Chapter 4 – Program Integrity, similarly provides a detailed list of "Examples of Medicare Fraud," including those at issue here:

- "Incorrect reporting of diagnoses or procedures to maximize payments;"
- "Billing for services not furnished and/or supplies not provided."

[5] A 2013 e-mail string also confirms that PVA knows its charges must be billed under the physician who actually read the study. *See* Ex. 16 ("Dr. Macris is the one who read the study, so the lab should be billed under him.").

- "Misrepresenting dates and descriptions of services furnished or the identity of the beneficiary or the individual who furnished the services;"

Ex. 205, § 4.2.1. These publications confirm the materiality to Medicare of these practices.

PVA argues that the Government is aware of PVA's practices but has continued to pay PVA, and therefore its violations could not have been material. In support of its argument, PVA points to the fact that the Department of Justice investigated the allegations in Relators' complaint, including by issuing a subpoena, receiving documents, and having a meeting. Under PVA's logic, any non-intervened FCA case would fail the materiality test. This is illogical, and unsupported by caselaw. As repeatedly emphasized by the courts, a declination to intervene should not be construed as a comment by the government on the merits of a claim. *See United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006) (the United States' "absence from the fray" does not mean that the relator's claims lack merit); *United States ex rel. Chandler v. Cook County*, 277 F.3d 969, 974 n.5 (7th Cir. 2002), *aff'd,* 538 U.S. 119 (2003) ("there is no reason to presume that a decision by the Justice Department not to assume control of the suit is a commentary on its merits. The Justice Department may have myriad reasons for permitting the private suit to go forward including limited prosecutorial resources and confidence in the relator's attorney."); *United States ex rel. El-Amin v. George Washington University*, 533 F. Supp. 2d 12, 21-22 (D.D.C. 2008) ("assuming the government looked unfavorably upon each qui tam action in which it did not intervene would seem antithetical to the purpose of the qui tam provision – to encourage private parties to litigate on behalf of the government . . . [and inaction cannot be seen] as evidence of how the government appraised the merits of the relator's case").

Moreover, PVA has submitted no admissible evidence of the government's *actual* knowledge. As the First Circuit explained on remand in *Escobar*, for purposes of materiality, there is a vast difference between the government being made aware of allegations, and having actual knowledge of fraud:

> [M]ere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance. Additionally, there is no evidence in the complaint that MassHealth, the entity paying Medicaid claims,

> had actual knowledge of any of these allegations (much less their veracity) as it paid UHS's claims. Because we find no evidence that MassHealth had actual knowledge of the violations at the time it paid the claims at issue, we need not decide whether actual knowledge of the violations would in fact be sufficiently strong evidence that the violations were not material to the government's payment decision so as to support a motion to dismiss in this case.

*United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016).

Furthermore, PVA's argument is at odds with its overall insistence that it did nothing wrong, and that there exists no clear guidance, as explained in another post-*Escobar* decision:

> This Court doubts that the hospital industry would warmly welcome a rule that required the Government to cut off hospital funding whenever a qui tam action is filed or forfeit its right to seek reimbursement. "The Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing. To this day, defendants claim they did not have the requisite scienter to violate the FCA. All the evidence defendants have put forth in support of their scienter cuts against their materiality argument that the Government was aware of AKS/FCA violations as early as 2011 but nonetheless continued to pay claims." *United States ex rel. Lutz v. Berkeley Heartlab, Inc.*, 2017 WL 4803911 (D. S.C. Oct. 23, 2017).

*United States ex rel. Longo v. Wheeling Hosp., Inc.*, No. 5:19-CV-192, 2019 WL 4478843, at *7 (N.D.W. Va. Sept. 18, 2019).

The government's declination in this case is simply irrelevant, as the *Escobar* test does not apply here. But even under the *Escobar* framework, PVA's claims to Medicare indicating that it "had provided more services" than it had, constitutes "plain and obvious materiality [that] went to the heart" of PVA's "ability to obtain reimbursement from Medicare." *Ruckh v. Salus Rehab., LLC*, 963 F.3d 1089, 1105 (11th Cir. 2020).

PVA's failures are not trivial. Medicare pays for services rendered—past tense. The CMS-1500 form is clear that it is for billing services rendered—past tense. *See, e.g.,* Ex. 40, at p. 2 (certifying that the "services on this form were medically necessary and personally furnished by me…") (emphasis added).

Moreover, Medicare pays only for services that were medically necessary. It does not reimburse for diagnostic tests used for "screening" purposes; i.e., patients must have a symptom or history that requires the vascular studies to be performed. *See* Ex. 39 (LCD L35397) at

ALEXANDER000074; App. No. 72. If a physician's interpretation is performed days, weeks, or months after an ultrasound, then the test must not have been necessary in the first place. As described above in Section II.E.4, without a physician's interpretation, a vascular study is meaningless, and puts patient health and safety at risk.

PVA's internal documents, and the testimony of its personnel, confirm the importance and materiality of performing the studies promptly, and not billing until interpretation was complete. For example, as detailed in Section II.E.1, in documents related to the 2017 compliance project, PVA's Vascular Lab Committee laid out three motives for the "[t]ransition to billing after studies are read," as (1) "Ensure billed to appropriate physician," (2) "Ensure no audit requests for incomplete medical records," and (3) "Allow for docs to read each others stuff." Ex. 31 at DEF007698; App. No. 47. PVA thus knew these issues were important, and even understood why. Similarly, PVA closely monitored its delays in physician read times, and in the hospital context, is essentially fully compliant with the rules and industry standards. *See, supra,* § II.E.3.c; App. No. 72.

Any suggestion that PVA's practices were "harmless error" is both irrelevant, and simply wrong. Medicare pays only for services rendered, and for good reason—to prevent billing fraud, ensure medical necessity, and ensure good patient care.

**D. PVA's claims caused the government to pay out significant moneys.**

PVA disputes liability, but does not dispute Relators' damages calculations. Those calculations are summarized here again, as follows.

**"Testing-Only":** As to the "testing only" patients, single damages as to federal payers total $820,893, on 8,757 false claims. *See* Ex. 207 (data extracted from Exhibits 10a and 10b of the Second Supplemental Report of Dr. Nye, with non-federal and non-Medicare payors filtered out[6]).

[6] These figures are based on conservative assumptions when filtering out non-Medicare-related payors from Dr. Nye's results. Accordingly, should the case proceed to trial, these figures may increase.

**"Double Dipping":** As to testing and E/M visit patients for which PVA submitted vascular study global CPT codes without a separate, stand-alone physician interpretation and report, single damages as to federal payers total $5,625,548, on 55,566 false claims for vascular studies. *See* Ex. 207 (data extracted from Exhibits 4d Supplemental and 11 of the Second Supplemental Report of Dr. Nye, with non-federal and non-Medicare payors filtered out).

**Wrong Provider:** As to all of the vascular study charges in the "testing only" and "double dipping" categories, where PVA submitted a vascular study global CPT code under the name of a physician who did not ultimately read the study, single damages to federal payers total $167,870, on 1,690 false claims. *See* Ex. 207 (data extracted from Exhibits 9a and 9b of the Second Supplemental Report of Dr. Nye, with non-federal and non-Medicare payors filtered out).

Treble damages and statutory penalties on the foregoing figures are mandatory. *See* 31 U.S.C. § 3729(a)(1).

**E. The False Claims Act is Constitutional.**

In a last ditch effort, PVA asserts unsupported and unsound constitutional arguments. *See* Oppo. at 24. As PVA acknowledges, *Riley v. St. Luke's Episcopal Hospital*, 252 F.3d 749 (5th Cir. 2001) is controlling. The Fifth Circuit there, *en banc*, held that pursuit of FCA claims where the government does not intervene (1) does not interfere with the President's constitutionally assigned functions under Article II's Take Care Clause; (2) does not violate the Appointments Clause ("We are persuaded that this argument holds even less vitality than the arguments made about the Take Care Clause, given that *qui tam* relators are not officers of the United States"); and (3) does not violate separation of powers principles. *See Riley,* 252 F.3d at 753-57.

PVA cannot seek refuge in the dissent of two Justices deviating from the majority's *en banc* opinion, which has been reiterated in numerous cases. *See, e.g., Luka v. Procter and Gamble Co*., 785 F. Supp. 2d 712 (N.D. Ill. 2011).

## III. CONCLUSION

For the foregoing reasons, Relators respectfully request that the Court grant Summary Judgment, or in the alternative, partial Summary Judgment.

Dated: September 18, 2020

By: */s/ Justin T. Berger*

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 18th day of September, 2020, I electronically filed the foregoing instrument with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following counsel of record:

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